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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,341

04/22/2005

Kurt Frimann Berg

BERG3

1525

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,341	<b>Applicant(s)</b> BERG, KURT FRIMANN	
	<b>Examiner</b> Taofiq A. Solola	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1,3,5-27,58-71,74-78 and 81-92 is/are pending in the application.
- 4a) Of the above claim(s) 58-71,74-78 and 81-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 3, 5-27,84-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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Claims 1, 3, 5-27, 58-71, 74-78, 81-92 are pending in this application.

Claims 2, 4, 28-57, 72-73, 79-80 are cancelled.

***Response to Restriction***

Applicant asserts the invention is patentable over the prior art and therefore the non-elected invention should be rejoined. This is not persuasive because the invention is in fact not patentable over prior arts of record.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5-27, 84-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al., WO 02/09699.

Applicant claims compositions comprising purified flavonoids and purified menthol. In preferred embodiments the compositions comprise different flavonoids derivatives such as troxerutin and veneruton, further comprise zinc metal complex/salts, and compositions essentially free of one/more of menthone, methyl acetate, limonene and neomenthol. Some of these are minor constituents of peppermint oil, which are not known or shown in the specification to be injurious. The major constituent of peppermint oil is menthol. The term "essentially free" implies the compositions are not 100 % free of the listed compounds. The compositions are for treating common cold.

*Determination of the scope and content of the prior art (MPEP 2141.01)*

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Berg et al., teach compositions comprising purified flavonoids and zinc metals complex/salts and optionally peppermint oil. The zinc metals are the same as in the instant invention and the compositions may comprise different flavonoids derivatives such as troxerutin, veneruton, etc. The compositions are for treating common cold. See page 5, paragraph 7 to page p, paragraph 3. See also the abstract.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Berg et al., is the level of purities of menthol in the compositions.

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

However, changing the level of purity of menthol is an obvious modification available to the preference of an artisan, and does not rise to the level of invention under the US patent practice. It is a mere optimization of a variable, which is not patentable absent unexpected result due to the variable, which is different in kind and not merely in degree from that of the prior art. *In re Aller*, 22 F.2d 454, 105 USPQ 233 (CCPA, 1955). Therefore, the instant invention is prima facie obvious from the teaching of Berg et al. One of ordinary skill in the art would have known to change the levels of purities of menthol at the time this invention was made. The motivation is to obtain a purer composition.

Alternatively, none of the flavonoids, zinc metal complex/salts and menthol is applicant's invention. They are in the public domain prior to the time the instant invention was made. Applicant has done no more than combine separate but well-known inventions. While the combination may perform a useful function it did no more than what they would have done (mode of action) separately. *In re Anderson*, 396 U.S. 57, 163 USPQ 673 (1969) cited in *KSR Int. Co. v. Teleflex Inc*, 550 U.S. ----, 82 USPQ2d 1385 (2007). When a patent simply arranges old elements with each performing the same function it had been known to perform and yields

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predictable result, the combination is obvious. *In re Sakraida*, 425 US 273, 189 USPQ 449 (1976) cited in *KSR, supra*. A patent for such combination “obviously withdraws what is already known into the field of its monopoly.” *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 187 USPQ 303 (1950), cited in *KSR, supra*.

### ***Response to Argument***

Applicant's arguments filed 3/11/08 have been fully considered but they are not persuasive. To establish unexpected result, Applicant contends menthol in the composition of Berg et al., is for flavoring while in the instant it is for treating common cold. This is not persuasive because both compositions are for treating common cold. Historically, both flavonoids and menthol are widely use in common cold remedies. For example, see WO 01/03681 and Eccles, J. Pharm. Pharmacol. (1994) pp. 618-630. Applicant also asserts that TSM should be applied in the instant. This is the rigid rule of TMS that was invalidated recently in *KSR, supra*. According to *KSR* where the prior art fails to set forth TSM other factors (set forth in *KSR*) may be considered.

The Examiner has no opinion on the choice between flagrant, etc. Applicant may submit reference BC and BD on a new IDS for consideration.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

May 26, 2008